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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/911,824      | 08/15/1997  | JOHN R. HACKETT, JR. | 6165.US.01          | 4028             |

23492 7590 11/15/2001

ABBOTT LABORATORIES  
DEPT. 377 - AP6D-2  
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EXAMINER

HILL, MYRON G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1648

DATE MAILED: 11/15/2001

21

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 08/911,824             | HACKETT, JR. ET AL. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Myron G Hill           | 1648                |  |

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The examiner acknowledges the response of 13 September 2001, paper #20.

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

#### ***Reconsideration of Previously Allowable Subject Matter***

The indicated allowability of claim 1 is withdrawn, on reconsideration, see below.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "[a]n isolated HIV-1 Group O polypeptide having an amino acid sequence consisting essentially of the sequence of Figure 1 (SEQ ID NO:61)." The term "consisting essentially of" is defined in the specification page 9 lines 33-35 to include "variant polypeptides whose structural and functional characteristics of which remain substantially the same." It is not clear at all what characteristics can change and still be "substantially the same." Therefore the metes and bounds of the claimed protein are

Art Unit: 1648

indefinite. Claim 2 recites "[a]n isolated HIV-1 Group O polypeptide comprising an immunoreactive portion of a polypeptide of claim 1" and is indefinite because it depends on claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the full scope of the claimed invention.

Claim 1 is drawn to Group O env proteins which vary from SEQ ID NO:61, as long as they are in some manner "substantially the same" in structural and functional characteristics. The claim encompasses Group O env proteins that have not yet been discovered, and the specification provides no basis to predict the structural and functional characteristics of the as-yet undiscovered Group O env proteins. Claim 2 is even more broadly drawn, to any Group O env protein which shares an epitope with any of the claim 1 proteins. Therefore, the claims are drawn to a genus of proteins, and the specification only describes one species within the genus. The specification does not reasonably convey possession of the full gamut of Group O env proteins claimed, from the description of one species within the genus.

***Claim Objections***

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 2 recites "[a]n isolated HIV-1 Group O polypeptide having an amino acid sequence comprising immunoreactive portion of a polypeptide of claim 1." It is drawn to any HIV-1 Group O *env* polypeptide which shares any immunogenic portion of SEQ ID NO:61. It therefore encompasses Group O proteins which share a single epitope with SEQ ID NO:61. Claim 2 includes proteins that are outside the the scope of claim 1, since the extent of variation of Group O proteins can go beyond those that have "structural and functional characteristics substantially the same" as SEQ ID NO:61.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delaporte et al (AIDS 1996, vol. 10 pages 903-910).

Art Unit: 1648


The specification states that sequences 80% homologous to SEQ ID NO:61 (page 9, lines 35-36) would be included in the scope of the polypeptide "consisting essentially of SEQ ID NO:61." Delaporte teaches a DNA sequence (sequence deposited in EMBL X96526, page 905, column 2, second paragraph from bottom) encoding an HIV-1 Group O env polypeptide that is 83.5% identical to SEQ ID NO:61. See attached amino acid sequence comparison. Therefore, the reference explicitly suggests an isolated HIV-1 Group O env polypeptide which meets the bounds of the broadly claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill  
Patent Examiner  
November 9, 2001

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800** 7600